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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 01/05/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,376

Applicant(s)

BODNER, JEFFREY P.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/24/03 (Amendment and RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 11/24/03 has been entered.

### ***Response to Amendment filed 11/24/03***

2. The Applicant amended of independent claims 1, 11, 18 and 24 to overcome the rejection of record, hence a new grounds of rejection is established in the subsequent paragraphs.

### ***Claim Rejections - 35 USC § 103***

3. Claim 1-4, 6-9, 11-14, 18-20, 22, 24, 25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al. (US 5545201) in view of Barcel (US 5275171) and further in view of Cobian et al. (US 5796044).

Helland et al. disclose an implantable bipolar pacing lead with two coiled conductors (160, 162) and an electrode assembly with an extendable electrode (142) and an insulating sheath (124) (figure 6; col. 2 @ 32-54; col. 3 @ 13-17; col. 4 @ 55 – col. 5 @ 15).

As to claims 1, 2, 7 and 11, the first and/ or second conductors are a wire or a coiled conductor (col. 3 @ 13-17).

As related to claims 3, 4, 6, 11, 13, 19 and 24, the insulation sheath (164) is read as a sleeve or tube of redundant insulation (figure 6).

As related to claims 1, 8, 11, 14, 18 and 25, the electrode assembly contains a fixed or movable helix electrode (144) coupled to the second conductor. The electrode is rotated and positioned using a stylet and the outer sheath (col. 2 @ 49-53 and 58-60; col. 4 @ 58-63; col. 5 @ 9-13).

As discussed in the previous five paragraphs, Helland discloses the claimed invention except for the conductors including one or more filars (claims 1, 11, 18 and 24).

Barcel teaches conductor construction using a multifilar conductor for the purpose of providing electrical redundancy within the lead to enable electrical conduction to continue even when a single filar is fracture. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a multifilar conductor in the Helland et al. system in order to avoid expensive and potentially dangerous lead replacement necessitated by the fracture of the implanted conductor (col. 1 @ 37-54).

As discussed in the previous six paragraphs, modified Helland discloses the claimed invention except for the second conductor having an outer surface surrounded by an insulative coating such that a cross-section of the outer filar surface is surrounded by an insulative coating (claims 1, 11, 18 and 24).

Cobain et al. teach conductor construction using coiled conductors having individually insulated coil wires for the purpose of providing electrical isolation and protection for the conductors. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a second conductor having an outer surface surrounded by an insulative coating in the Helland et al. system in order to insulate the second conductor from the impact of body fluids encountered during lead insertion, hence preventing metal migration and the breakdown of the lead insulation (figures 2 and 9; col. 2 @ 25-30; col. @ 35 – col. 4 @ 23; col. 8 @ 29-48; col. 10 @ 53-63).

4. Claims 5, 21, 23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al. (US 5545201) in view of Barcel (US 5275171) and further in view of Cobian et al. (US 5796044) and further in view of Altman et al. (US5845396). As discussed in paragraph 2 of this action, modified Helland et al. disclose the claimed invention except for the insulation being a non-silicon/ polyimide material (claims 5 and 21), the insulation being heat-shrunk PTFE / ETFE material (claims 23 and 27), and the insulative coating being polyurethane (claim 26).

As to claims 5 and 21, Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10;

col. 2 @ 34-36).

As to claims 23 and 27, Altman et al. teach a lead with heat-shrunken PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunken PTFE/ ETFE insulated conductors in the modified Helland et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

As to claim 26, Altman et al. teach signal conduction using a conductor with a polyurethane coating for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

5. Claims 10, 15-17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al. (US 5545201) in view of Barcel (US 5275171) and further in view of Cobain et al. (US 5796044) and further in view of Doan (US 5425755).

As discussed in paragraph 3 of this action, modified Helland et al. disclose the claimed invention except the insulative coating being ETFE (claims 10 and 15-17), and the tubing being polyurethane (claim 22).

As to the insulative coating being ETFE, Doan teaches the lead insulation using a biocompatible TEFLON <sup>TM</sup> coating, such as ETFE, for the purpose of minimizing the frictional resistance between the coated coil and the surrounding insulation. ETFE is a material well known in the conductor art for use as a conductor insulator (US 5845396 to Altman et al. – col. 7 @ 11-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an insulative coating of ETFE in the Doan system in order to reduce the coefficient of friction between the outer coil and outer insulation so the lead has increased flexibility facilitating the positioning and fixation in the heart, and so the torque associated with the inner coil and tubing is reduced when the helix electrode is extended or retracted to minimize damage to the lead (abstract; col. 2 @ 17-26; col. 4 @ 5-10).

As to the tubing being polyurethane, Doan teaches lead construction using polyurethane tubing for the purpose of minimizing the frictional resistance. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a polyurethane tube in the Helland et al. system in order to minimize the torque transfer between the coated coils and insulation so the lead can be placed in the heart and the electrode secured with optimum ease and minimum stress and strain on the lead (col. 2 @ 17-26).

***Statutory Basis***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

FP  
12/24/03

Angela D. Sykes

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